

United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

26951-27000

[Approved by the Acting Secretary of Agriculture, Washington, D. C., June 15, 1937]

26951. Misbranding of Bromo-Foam. U. S. v. Chancey A. Jones (Bromo-Foam Co.). Plea of nolo contendere. Fine, \$50 and sentence of imprisonment for 1 year; sentence of imprisonment suspended and defendant placed on probation for 5 years on payment of fine. (F. & D. no. 31345. Sample no. 40801-A.)

This case involved an interstate shipment of an article, labeled "Bromo-Foam", the package and the label on the containers of which bore and contained false and fraudulent curative and therapeutic claims and a false and misleading representation that the active ingredients of the article were bromides.

On February 5, 1934, the United States attorney for the Northern District of Ohio, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Chancey A. Jones, trading as the Bromo-Foam Co., Tiffin, Ohio, charging shipment by said defendant in violation of the Food and Drugs Act as amended, on or about May 20, 1933, from the State of Ohio into the State of Indiana of a quantity of Bromo-Foam that was misbranded.

Analysis of the article showed that it consisted essentially of sodium bicarbonate (65 percent), sodium chloride (3.87 percent), sodium salicylate (3.44 percent), sodium bromide (2.90 percent), caffeine (0.51 percent), and citric acid, flavored with oil of peppermint.

The article, contained in 24 tubes all enclosed in a carton, was alleged to be misbranded in that statements regarding its curative and therapeutic effects, borne on the tube labels, carton, an accompanying display carton, and display strip, falsely and fraudulently represented that it would be effective to promote real health; effective as a treatment, remedy, and cure for exhaustion, indigestion, ailments of the head and stomach, and sick stomach; effective as a relief for headache due to any nervous or mental strain, stomach disorders caused by eating, biliousness, and indigestion; and effective as a neutralizing agent. The article was alleged to be misbranded in that the statement "Bromo-Foam", borne on the tube labels, carton, accompanying display carton, and display strip, was false and misleading in that it represented that the active ingredients of the article consisted of bromides; whereas in fact the active ingredients of the article did not consist of bromides.

On January 21, 1937, the defendant entered a plea of nolo contendere; and the court imposed a fine of \$50 and a sentence of imprisonment for 1 year, but suspended the sentence of imprisonment and placed the defendant on probation for 5 years on payment of the fine.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26952. Misbranding of Eczematone and Eczematone Ointment. U. S. v. 92 Bottles and 1 Jug of Eczematone. Tried to the court. Judgment of condemnation and destruction; product released under bond. U. S. v. 55 Jars of Eczematone Ointment and 115 Bottles of Eczematone. Consent decree of condemnation; products released under bond. (F. & D. nos. 32254, 32255, 32256. Sample nos. 61552-A, 61555-A, 61558-A.)

The labels of these products bore false and fraudulent representations regarding their curative and therapeutic effects.

On March 10, 1934, the United States attorney for the Northern District of Texas, acting upon reports by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of 207 bottles of various sizes and

one 1-gallon jug of Eczematone and 55 jars of Eczematone Ointment at Amarillo, Tex. It was alleged that the articles had been shipped in interstate commerce, the Eczematone on or about January 23, April 12, July 31, and November 6, 1933, and the Eczematone Ointment on or about March 4, September 7, and October 30, 1933, by the Barlow Chemical Association from Oklahoma City, Okla., and that they were misbranded in violation of the Food and Drugs Act as amended.

Analysis of a sample of Eczematone showed that it consisted essentially of mercuric chloride (corrosive sublimate, 0.3 gram per 100 milliliters), a trace of boric acid, alcohol (84 percent by volume), and water. Analysis of the Eczematone Ointment showed that it consisted essentially of mercury and a mercury compound incorporated in an ointment base.

The bottles containing the Eczematone were labeled variously in part as follows: "Eczematone * * * The Greatest Discovery of the Age for Skin and Scalp Disease * * * For Eczema, Acne and Pimples. * * * A Panacea For Scalp Disease Directions—Bathe freely the parts affected twice a day or as needed, always rubbing gently until the surface is dry. Remember it must be applied very freely, either for Scalp Disease or for Skin Trouble. In some very stubborn cases of Eczema, it is sometimes necessary to use our Eczematone Ointment at night and wash it off in the morning with Eczematone Liquid. * * * For Dandruff and Falling Hair Just apply Eczematone freely to the roots of the hair. Massage in well every other day for a week. Then shampoo the hair thoroughly with Eczematone Liquid Soap. Dry the hair and apply another application of Eczematone immediately. In severe cases, repeat the following week. After that, a good application of Eczematone once a week, as a preventative, and your scalp troubles are over. * * * Eczematone * * * For the following ailments, always use Eczematone. Eczema, Acne, Pimples, Tetters, Ringworm, Barber's Itch, Dandruff, Falling Hair, * * * Sore * * * Aching feet. Just apply freely 2 or 3 times a day, or as needed and see for yourself, the wonderful results * * * Eczematone * * * For Skin and Scalp Disease * * * For Eczema, Acne and Pimples. * * * Directions—Apply freely to parts affected, 2 or 3 times a day as needed, always rubbing gently until surface is dry. Remember it must be used very freely, either for Skin or Scalp troubles. In severe cases of Skin Troubles, it is sometimes advisable to use Eczematone Ointment at night, and wash it off in the morning with Eczematone Liquid. * * * For Dandruff and Falling Hair Just apply Eczematone freely to the roots of the hair. Massage in well every other day for a week. Then shampoo the hair thoroughly, preferably with Eczematone shampoo [or Soap]. Dry the hair, and apply another application of Eczematone, immediately. In severe cases, repeat the following week, after that, a good free application once a week, as a preventative. * * * Eczematone * * * For the following Ailments, try Eczematone. Eczema, Acne, Pimples, Tetters, Ringworm, Barber's Itch, * * * Aching Feet. Just apply freely, 2 or 3 times a day as needed, and see the wonderful results for yourself."

The Eczematone was alleged to be misbranded in that the aforesaid statements regarding its curative or therapeutic effects borne on the labels of the bottles, falsely and fraudulently represented that it was capable of producing the effect claimed in said statements.

The jars containing the Eczematone Ointment were labeled in part as follows: "Eczematone * * * Especially prepared for Eczema, Acne, Pimples, Scrofula Sores, and any kind of Skin Troubles of any nature. Directions Apply freely to parts affected and rub in thoroughly until the surface is nearly dry. Once or twice a day as required. In severe cases apply this Ointment at night, and wash off in the morning with Eczematone Liquid. * * * A guaranteed Pile Remedy."

The Eczematone Ointment was alleged to be misbranded in that the aforesaid statements regarding its curative and therapeutic effects, borne on the jar labels, falsely and fraudulently represented that it was capable of producing the effects claimed in said statements.

On September 17, 1934, the Barlow Chemical Association having intervened as claimant, the case *U. S. v. 92 Bottles and 1 Jug of Eczematone* was tried to the court, a jury having been waived, and on September 26, 1935, judgment of condemnation was entered and the product was ordered destroyed. On October 23, 1935, the product was released under bond conditioned that it not be disposed of contrary to law.

In the cases *U. S. v. 55 Jars of Eczematone Ointment* and *115 Bottles of Eczematone*, the Barlow Chemical Association, claimant, having admitted the allegations of the libel and having consented to a decree, judgment of condemnation was entered on June 4, 1936, and on June 8, 1936, the product was ordered released under bond conditioned that it not be disposed of contrary to law.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26953. Misbranding of Compressed Tablet Thyroid Glands. U. S. v. William H. Rorer, Inc. Tried to the court. Judgment of guilty; fine, \$10. (F. & D. no. 32919. Sample no. 58666-A.)

These tablets contained a greater quantity of desiccated thyroid than was represented on the label.

On October 1, 1934, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against William H. Rorer, Inc., Philadelphia, Pa., charging shipment by said corporation on or about October 30, 1933, in violation of the Food and Drugs Act, from the State of Pennsylvania into the State of New Jersey, of a quantity of Compressed Tablet Thyroid Glands that were misbranded.

The article was alleged to be misbranded in that the statement, "Thyroid Glands Desiccated Each Tablet Represents * * * 2 Grains", borne on the bottle labels, was false and misleading in that it represented that each of the tablets contained 2 grains of desiccated thyroid; whereas in fact each of the tablets contained more than 2 grains of desiccated thyroid.

On December 16, 1936, after trial of the case to the court on February 19, 1936, and a jury having been waived, judgment was rendered in the following opinion:

KIRKPATRICK, District Judge: This was a criminal prosecution under Section 2 of the Food and Drugs Act as amended. It was tried to the Court, a jury trial having been waived. The facts are quite simple, and by the verdict which I shall enter, they are determined as follows:

The defendant sold a bottle containing one hundred 4-grain thyroid tablets. The label represented that the tablets contained an average of 2 grains of thyroid each. I find as a fact that the tablets contained an average of not less than two and forty-one hundredths grains of the essential thyroid element—an excess of 20 percent over the content as represented.

No evidence was presented by either side to show whether or not such an excess of thyroid, of the existence of which the user or prescribing physician would in all probability be ignorant, could be dangerous or harmful.

At the trial I held that the defendant could not be convicted of adulteration. The question remains whether it is guilty of misbranding.

The pertinent words of the statute are (Section 2) "Any person * * * who shall sell * * * any * * * misbranded * * * drugs * * * shall be guilty of a misdemeanor, etc."; (Section 8) "That the term 'misbranded' as used herein shall apply to all drugs * * * the package or label of which shall bear any statement, * * * regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular * * *."

If the statute be interpreted literally the defendant has violated it. His statement that each tablet contained 2 grains of thyroid was in fact a false statement regarding the articles, their ingredients, and the substances contained therein.

It is obvious, however, that one must stop somewhere short of an absolutely literal construction. Thus, if a man sells a pound and a quarter of pure butter under a label representing that the package contained one pound, or, if this defendant had put 105 tablets in his bottles of 100, it would be beyond reason to hold that the Act had been violated.

The misrepresentation here involved, however, does not relate to the number of articles sold or the quantity of a uniform substance. In *United States vs. Johnson*, 221 U. S. 488, the Supreme Court, in holding that the statute did not cover false or fraudulent claims of merit or of the curative effect of a drug, went on to say that the phrase (referring to the definitions of misbranding) "is aimed not at all possible false statements, but only at such as determine the identity of the article, possibly including its strength, quality and purity." This seems to cover the case at hand. The defendant's representation, upon